Subject: Outpatient Cardiac Rehabilitation

Policy Number: NMP530

Effective Date*: April 2014

Updated: January 2017

This National Medical Policy is subject to the terms in the IMPORTANT NOTICE at the end of this document

For Medicaid Plans: Please refer to the appropriate State’s Medicaid manual(s), publication(s), citation(s), and documented guidance for coverage criteria and benefit guidelines prior to applying Health Net Medical Policies

The Centers for Medicare & Medicaid Services (CMS)
For Medicare Advantage members please refer to the following for coverage guidelines first:

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<tr>
<th>Use</th>
<th>Source</th>
<th>Reference/Website Link</th>
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<tbody>
<tr>
<td>X</td>
<td>National Coverage Determination (NCD)</td>
<td>Intensive Cardiac Rehabilitation (ICR) Programs (20.31); Ornish Program for Reversing Heart Disease (20.31.2); The Pritikin Program (20.31.1); <a href="http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx">http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx</a></td>
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<td>X</td>
<td>Article (Local)*</td>
<td>Outpatient Cardiac Rehabilitation: <a href="http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx">http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx</a></td>
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Decision Memo for Cardiac Rehabilitation Programs (CAG-00089R): http://www.cms.gov/medicare-coverage-database/details/nca-decision-
Outpatient Cardiac Rehabilitation

January 17, 2017


Center for Medicare & Medicaid Services (CMS). Medicare NCDs and National Coverage Manuals apply to ALL Medicare members in ALL regions.

Medicare LCDs and Articles apply to members in specific regions. To access your specific region, select the link provided under “Reference/Website” and follow the search instructions. Enter the topic and your specific state to find the coverage determinations for your region. *Note: Health Net must follow local coverage determinations (LCDs) of Medicare Administration Contractors (MACs) located outside their service area when those MACs have exclusive coverage of an item or service. (CMS Manual Chapter 4 Section 90.2)

If more than one source is checked, you need to access all sources as, on occasion, an LCD or article contains additional coverage information than contained in the NCD or National Coverage Manual.

If there is no NCD, National Coverage Manual or region specific LCD/Article, follow the Health Net Hierarchy of Medical Resources for guidance.

Current Policy Statement
Health Net, Inc. considers medically supervised outpatient cardiac rehabilitation medically necessary when prescribed by a physician for individuals who have experienced one or more of the following conditions within the previous year:

1. Myocardial infarction (MI)/acute coronary syndrome (ACS)
2. Coronary artery bypass grafting (CABG)
3. Percutaneous coronary intervention (PCI) [e.g., transluminal coronary angioplasty (PTCA), coronary stenting]
4. Chronic stable angina
5. Heart valve surgical repair or replacement
6. Heart or heart/lung transplantation
7. Stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35% or less and New York Heart Association class II through IV symptoms despite being on optimal heart failure therapy for at least 6 weeks. Stable patients are defined as patients who have not had recent (≤6 weeks) or planned (≤6 months) major cardiovascular hospitalizations or procedures.
8. Placement of a ventricular assist device
9. Survivors of sudden cardiac death, sustained ventricular tachycardia or ventricular fibrillation
10. Individuals with peripheral artery disease and intermittent claudication

The New York Heart Association (NYHA) Functional Classification

<table>
<thead>
<tr>
<th>Class I</th>
<th>Patients with cardiac disease but resulting in no limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea or anginal pain.</th>
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</thead>
<tbody>
<tr>
<td>Class II</td>
<td>Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea or anginal pain.</td>
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<tr>
<td>Class III</td>
<td>Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain.</td>
</tr>
<tr>
<td>Class IV</td>
<td>Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort increases.</td>
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NOTE: The risk of cardiovascular complications from exercise training should be evaluated prior to an exercise program. It is an integral component of the rehabilitative process because it provides for the establishment of appropriate specific safety precautions, target exercise training heart rates, and initial levels of exercise training work rates. Exercise testing is also important in the risk stratification process. The American Heart Association recommends that an exercise test should be performed on all cardiac patients entering an exercise training program and should be repeated at least annually or at any time the individual’s condition warrants.

Cardiac Rehabilitation Sessions
Various recommendations exist regarding the number of electrocardiogram-monitored cardiac rehabilitation sessions that are necessary and reasonable in an exercise training program. There are no controlled clinical trials that have specifically...
evaluated this issue. Services delivered by an electrocardiogram-monitored cardiac rehabilitation program may be considered medically necessary for up to 36 sessions, and individuals typically participate two to three times per week, however, the fewest possible sessions should be used, and it is recommended that the classification as outlined below be used as a general guideline:

**Risk Classification for Exercise Training**

**Class A**: Apparently healthy individuals (i.e., individuals in whom there is no clinical evidence of increased cardiovascular risk of exercise), includes the following:

1. Children, adolescents, men <45 years, and women <55 years who have no symptoms or known presence of heart disease or major coronary risk factors
2. Men ≥ 45 years and women ≥ 55 years who have no symptoms or known presence of heart disease and with < 2 major cardiovascular risk factors.
3. Men > 45 years and women > 55 years who have no symptoms or known presence of heart disease and with > 2 major cardiovascular risk factors.

Activity guidelines: No restrictions other than basic guidelines. ECG and blood pressure monitoring not required. Supervision is not required although it is suggested that persons classified as Class A-2 and particularly Class A-3 undergo a medical examination and possibly a medically supervised exercise test before engaging in vigorous exercise.

**Class B (low risk)**: Presence of known, stable cardiovascular disease with low risk for complications with vigorous exercise, but slightly greater than for apparently healthy individuals.

Clinical characteristics (must include all of the following):

1. New York Heart Association class 1 or 2
2. Exercise capacity ≤ 6 METs
3. No evidence of congestive heart failure
4. No evidence of myocardial ischemia or angina at rest or on the exercise test at or below 6 METs
5. Appropriate rise in systolic blood pressure during exercise
6. Absence of sustained or nonsustained ventricular tachycardia at rest or with exercise
7. Ability to satisfactorily self-monitor intensity of activity

Medical supervision during initial prescription session is beneficial. Supervision by appropriate trained nonmedical personnel for other exercise sessions should occur until the individual understands how to monitor his or her activity. Medical personnel should be trained and certified in Advanced Cardiac Life Support. Nonmedical personnel should be trained and certified in Basic Life Support (which includes cardiopulmonary resuscitation).

ECG and blood pressure monitoring: Useful during the early prescription phase of training, usually 6 to 12 sessions.

**Class C**: Moderate to high risk for cardiac complications during exercise and/or unable to self-regulate activity or to understand recommended activity level.

Clinical characteristics (any of the following):
1. NYHA class 3 or 4.
2. Exercise test results:
   - Exercise capacity < 6 metabolic equivalents (METs)
   - Angina or ischemic ST depression at a workload < 6 METs
   - Fall in systolic blood pressure below resting levels during exercise
   - Nonsustained ventricular tachycardia with exercise
3. Previous episode of primary cardiac arrest (i.e., cardiac arrest that did not occur in the presence of an acute myocardial infarction or during a cardiac procedure).
4. A medical problem that the physician believes may be life-threatening

Medical supervision during all exercise sessions until safety is established. ECG and blood pressure monitoring: Continuous during exercise sessions until safety is established, usually >12 sessions.

**Class D**: Unstable disease with activity restriction (Exercise for conditioning purposes is not recommended)

This classification includes individuals with any of the following:

1. Unstable ischemia.
2. Severe and symptomatic valvular stenosis or regurgitation.
3. Congenital heart disease; criteria for risk that would prohibit exercise conditioning in patients with congenital heart disease should be guided by the 27th Bethesda Conference recommendations.
4. Heart failure that is not compensated.
5. Uncontrolled arrhythmias.
6. Other medical conditions that could be aggravated by exercise.

**Individuals with peripheral artery disease and intermittent claudication**
Supervised exercise training should be performed for a minimum of 30 to 45 minutes, in sessions performed at least 3 times per week for a minimum of 12 weeks.

**Ornish Cardiac Rehabilitation Program**
Health Net Inc., considers the Ornish cardiac rehabilitation program investigational for all Commercial Members since it does not offer any additional improvements over standard outpatient cardiac rehabilitation. Since this program is very intense and restrictive, the member's long-term adherence to the program is questionable. This program is covered for all Medicare Members who meet the criteria noted within the NCD for Ornish Cardiac Rehabilitation.
Definitions

ACS    Acute Coronary Syndrome
CABG   Coronary artery bypass grafting
PTCA   Percutaneous transluminal coronary angioplasty
PCI    Percutaneous coronary intervention
NYHA   New York Heart Association
CHD    Coronary heart disease
CVD    Coronary vascular disease
CR     Cardiac rehabilitation
SPP    Secondary prevention programs
AHA    American Heart Association
ACCF   American College of Cardiology Foundation
STEMI  ST- Elevation Myocardial infarction
LV     Left Ventricle
DT     Deceleration time
EF     Ejection fraction
ESV    End Systolic Volumes
EDV    End Diastolic Volumes
HRoL   Health related quality of life
UA     Unstable Angina
SIHD   Stable Ischemic Heart Disease
METs   Metabolic equivalents
HF     Heart failure
ET     Exercise training
QoL    Quality of life
HFPEF  Heart failure with preserved ejection fraction
UC     Usual care
LVAD   Left ventricular assist device
HT     Heart transplant
FMD    Flow mediated dilation
LMPs   Lifestyle modification programs
ICR    Intensive cardiac rehabilitation
METs   Metabolic equivalents

Codes Related To This Policy

NOTE:
The codes listed in this policy are for reference purposes only. Listing of a code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit documents and medical necessity criteria. This list of codes may not be all inclusive.

On October 1, 2015, the ICD-9 code sets used to report medical diagnoses and inpatient procedures have been replaced by ICD-10 code sets.
ICD-10 Codes
I20.1 Angina pectoris with documented spasm
I20.8 Other forms of angina pectoris
I20.9 Angina pectoris, unspecified
I21.01-I21.4 ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction
I24.0-I24.9 Other acute ischemic heart disease
I25.10 Atherosclerotic heart disease of native coronary artery without angina pectoris
I25.2 Old myocardial infarction
I25.5 Ischemic cardiomyopathy
I25.810 Atherosclerosis of coronary artery bypass graft(s) without angina pectoris
I25.811 Atherosclerosis of native coronary artery of transplanted heart without angina pectoris
I25.812 Atherosclerosis of bypass graft of coronary artery of transplanted heart without angina pectoris
I25.89 Other forms of chronic ischemic heart disease
I25.9 Chronic ischemic heart disease, unspecified
I50.1-I50.9 Heart failure
Z94.1 Heart transplant status
Z95.1 Presence of aortocoronary bypass graft
Z95.3 Presence of xenogenic heart valve
Z98.61 Coronary angioplasty status

CPT Codes
93798 Physician or other qualified health care professional services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per session)

HCPCS Codes
G0422 Intensive cardiac rehabilitation, with or without continuous ECG monitoring with exercise, per session
S9472 Cardiac rehabilitation program, nonphysician provider, per diem

Scientific Rationale – Update December 2014
Dr. Dean Ornish, a cardiologist, is the founder and president of the non-profit ‘Preventive Medicine Research Institute’ and Clinical Professor of Medicine at the University of California, San Francisco. Dr. Ornish’s Program for Reversing Heart Disease, also known as the Multisite Cardiac Lifestyle Intervention Program, the Multicenter Cardiac Lifestyle Intervention Program, or the Lifestyle Heart Trial Program, was initially described in the 1970’s and incorporates comprehensive lifestyle modifications including exercise, a low-fat diet, smoking cessation, stress management training, and group support sessions. Over the years, the Ornish Program has been refined but continues to focus on these specific risk factors to slow, stop and even reverse the progression of coronary artery disease. The Ornish diet was rated #1 for heart health by U.S. News & World Report in 2011 and 2012.

Dr. Ornish’s program for Reversing Heart Disease is currently offered in hospitals, clinics, and physician offices that Medicare and other private insurance companies are covering. There are two steps in becoming a certified provider:

1. The Health Care professionals should submit a request. The details of the training and certification will be available.
2. Once the individuals or sites have been trained and are certified by Dr. Ornish, they may enroll as an Intensive Cardiac Rehabilitation (ICR) provider.

For Medicare members, there is a National Coverage Determination (NCD) for ‘Ornish Program for Reversing Heart Disease (20.31.2), effective for claims with dates of service on and after August 12, 2010. The Centers for Medicare and Medicaid Services (CMS) has determined that the Ornish Program for Reversing Heart Disease meets the intensive cardiac rehabilitation (ICR) program requirements set forth by Congress in §1861(eee)(4)(A) of the Social Security Act and in our regulations at 42 C.F.R. §410.49(c) and, as such, has been included on the list of approved intensive cardiac rehabilitation (ICR) programs.

Clinical outcomes consistently demonstrate that the Ornish participants show improvements in:
- Blood pressure
- Weight
- BMI
- Cholesterol
- Angina
- Depression
- Vitality

Each Ornish certified site has a team of professionals to provide support, including Physician, Nurse Case Manager, Exercise Physiologist, Clinical Psychologist, Registered Stress Management Instructor, and Registered Dietician.

Patient Eligibility Criteria for Ornish Cardiac Rehabilitation, effective January 1, 2010, Medicare Part B will cover ICR program services for beneficiaries who have experienced one or more of the following:
- An acute myocardial infarction within the preceding 12 months.

Any of the following conditions with no specific time constraints:
- Coronary artery bypass surgery;
- Current stable angina pectoris;
- Heart valve repair or replacement;
- Percutaneous transluminal coronary angioplasty or coronary stenting;
- A heart or heart-lung transplant; or,
- Other cardiac conditions as specified through a national coverage determination (NCD).

Patients had better adherence and clinical outcomes than have ever been reported from a program of comprehensive lifestyle changes. Here are the latest findings from all of the 3,780 patients who went through the Ornish program at Highmark Blue Cross Blue Shield in Pennsylvania, Nebraska, and West Virginia as of October 2011:
- Overall attendance after 1 year was 87.9%;
- 45.2% of these patients had heart disease. (i.e., 34.0% had type 2 diabetes, and the others had only risk factors, high blood pressure, cholesterol, or weight), yet adherence was comparable in all categories of patients (85-90% after 1 year);
- The average patient lost 13.3 pounds in the first 12 weeks and 15.9 pounds after 1 year;
• Significant reductions in systolic blood pressure, diastolic blood pressure, total cholesterol, triglycerides, and LDL-cholesterol after 12 weeks were still significant after 1 year;
• Exercise capacity increased from 8.7 to 10.6 METS after 12 weeks (18% increase) and to 10.8 METS after one year (24% increase);
• Significant reductions in depression and hostility (the emotions most strongly linked with heart disease) after 12 weeks that were still significant after 1 year;
• Hemoglobin A1C in diabetics decreased from 7.4% at baseline to 6.5% after 12 weeks and 6.8% after one year (complications of diabetes such as blindness, kidney failure, heart disease, and amputations can be prevented when hemoglobin A1C is less than 7.0%);
• 96.5% of patients reported improvement in severity of angina (chest pain) after 1 year.

The categorized foods in the Ornish Program are arranged in Groups, from the most healthful (Group 1) to the least healthful (Group 5). This is called the Spectrum Approach and it’s all about freedom and choice, not about diet. The ‘Spectrum of Food Choices Table’ is just a guide. Other factors can change a food’s category, including the type of food, the amount of food, and other foods it’s consumed with.

• Group 1 foods are predominantly fruits, vegetables, whole grains, legumes, soy products, nonfat dairy, and egg whites in their natural forms, as well as some good fats that contain omega 3 fatty acids. These are the foods that are rich in good carbohydrates, fats, proteins and other protective substances. There are at least 100,000 substances in these foods that have powerful anti cancer, anti-heart-disease and anti-aging properties.

• Group 2 foods are also predominantly plant-based but somewhat higher in fat, predominantly monosaturated fat and polyunsaturated fat, such as avocados, seeds, nuts. Oils are included but in small amounts, since they are so dense in calories. Canola oil is a better choice than olive oil, as previously described, since canola oil contains some of the good omega 3 fatty acids and a better ratio of omega 6 fatty acids to omega 3 fatty acids than olive oil. Group 2 also includes foods canned in water (rather than sugary syrup), canned vegetables (if sodium is not too high), low-fat dairy 1%, decaffeinated beverages, low-sodium soy sauce, etc.

• Group 3 foods include some seafood, some refined carbohydrates and concentrated sweeteners, in moderation, some oils that are higher in saturated fat, oils that have a higher ratio of omega 6 fatty acids to omega 3 fatty acids, some reduced fat 2% dairy products, margarines free of trans fatty acids, sweeteners containing high fructose corn syrup, and higher sodium. In this group, there is preference to seafood that is higher in omega 3 fatty acids, such as salmon. Anchovies are high in omega 3 fatty acids but also high in fat if packed in oil. Wild salmon tends to be lower in mercury, dioxin, PCB’s, than farmed salmon, which should especially be avoided in pregnant and nursing women, although pregnant and nursing women should be sure to take omega 3 fatty acid supplement.

• Group 4 foods contain additional fat, higher fat animal protein and fewer protective nutrients. These include poultry, fish that are higher in mercury, whole milk/dairy products, margarine, mayonnaise, doughnuts, fried rice, pastries, cakes, cookies, and pies.

• Group 5 foods are, in general, the least healthful foods. They are the lowest in protective substances and are highest in “bad fats,” especially trans-fatty acids.
and saturated fat. This food group includes red meat in its various forms, egg yolks, fried poultry, fried fish, hot dogs, organ meats, butter, cream, and tropical oils.

In general, smaller portion sizes should be chosen when the individual is trying to lose weight, lower cholesterol or blood pressure, or reverse the progression of a chronic disease.

- **Nutrition Guidelines For Reversing Heart Disease:**
  - **Fat** — No more than 10% of calories are from fat. This is achieved by not adding any fats, oils, seeds, nuts, avocados, coconut and olives to a mostly plant-based diet. The 10% of calories from fat comes from fat that occurs naturally in grains, vegetables, fruit, beans, legumes and soy foods.
  - **Cholesterol** — No more than 10 milligrams of cholesterol per day. To meet this goal, non-fat dairy products are limited to 2 servings per day. Non-fat dairy products are optional. Soy products can be used instead of dairy products because they are cholesterol free.
  - **Animal Products** — Meat, poultry, fish and any products made from these foods are eliminated. Non-fat dairy foods (no more than 2 servings/day) and egg whites are included.
  - **Calories** — Unrestricted unless weight loss is desired. Small frequent meals spread throughout the day help avoid hunger and keep energy levels constant. Portion control will assist in reaching and maintaining a healthy body weight and controlling blood sugar levels.
  - **Sugar** — Permitted in moderation. No more than 2 servings/day including non-fat sweets. A serving is equivalent to 1 tablespoon or 12 grams of sugar.
  - **Caffeine** — All sources of caffeine are eliminated, including regular and decaffeinated coffees and teas, chocolate, cocoa, and regular or decaffeinated dark colas, with the exception of green tea. Caffeine’s effect on the central nervous system interferes with the mind body connection and therefore meditation and relaxation. Evidence from recent studies on tea shows that the health benefits of green tea outweigh the risks for most individuals. Green tea contains a variety of powerful antioxidants, or polyphenols, especially the flavonoids such as catechins, which may reduce the risk of many chronic diseases. Individuals with arrhythmia and elevated stress should still avoid any caffeinated beverage. Green tea should be limited to no more than 2 cups per day. Additionally, decaffeinated green tea can be consumed. Green tea that has been decaffeinated with the “effervescence” method (uses water and carbon dioxide), which preserves most of the polyphenols present in regular green tea. Caffeine-free herbal teas, grain-based coffees (i.e. Postum, Caffix and Roma), carob powder, Sprite, 7-Up or Ginger Ale are also good alternatives.
  - **Sodium** — Moderate salt use, unless medically indicated otherwise.
  - **Alcohol** — Allowed in small amounts but not encouraged. If consumed, enjoy one serving a day: 1.5 ounces liquor, 4 ounces wine or 12 ounces beer.
  - **Soy** — One serving per day of a “full-fat” soy food. A full-fat soy food is one that contains greater than 3 grams of fat per serving, with none of the fat coming from added fats or oils. Always read the label for portion sizes and ingredient content.
Supplements—A low dose multivitamin and mineral supplement with B-12 (without iron, if not of childbearing age), fish oil and, possibly upon the advice of a physician, calcium supplements. Antioxidant vitamins and folic acid are optional and are based on health history and nutritional intake of these nutrients.

People who have unstable angina or severe congestive heart failure should not take omega-3 fatty acids (i.e., fish oil), as taking fish oil may increase the risk of sudden cardiac death for people with these conditions.

Ornish et al. (1990) In a prospective, randomised, controlled trial to determine whether comprehensive lifestyle changes affect coronary atherosclerosis after 1 year, 28 patients were assigned to a group (i.e., low-fat vegetarian diet, stopping smoking, stress management training, and moderate exercise) and 20 to a usual-care control group. 195 coronary artery lesions were analyzed by quantitative coronary angiography. The average percentage diameter stenosis regressed from 40.0 (SD 16.9)% to 37.8 (16.5)% in the experimental group yet progressed from 42.7 (15.5)% to 46.1 (18.5)% in the control group. When only lesions greater than 50% stenosed were analyzed, the average percentage diameter stenosis regressed from 61.1 (8.8)% to 55.8 (11.0)% in the experimental group and progressed from 61.7 (9.5)% to 64.4 (16.3)% in the control group. Overall, 82% of the first group patients had an average change towards regression. Comprehensive lifestyle changes may be able to bring about regression of even severe coronary atherosclerosis after only 1 year, without use of lipid-lowering drugs.

Ornish et al. (1998) completed a study that included a very-low fat, vegetarian diet, moderate exercise and stress management intervention. The study population (194 CHD patients), all of whom were recommended for coronary revascularization, underwent aggressive lifestyle intervention and were compared with 139 matched control patients who had undergone revascularization. After 3 years, there was no difference between the groups for myocardial infarction, stroke, non-cardiac deaths or cardiac deaths; moreover, 150 of the 194 in the intervention group were able to avoid revascularization.

Frattaroli et al. (2008) investigated the effects of 12 weeks of this lifestyle intervention in 1152 CHD patients. To examine the effects of intensive lifestyle modification on symptom relief, the authors investigated changes in angina pectoris, coronary risk factors, quality of life, and lifestyle behaviors in patients with stable coronary artery disease enrolled in the multisite cardiac lifestyle intervention program, an ongoing health insurance–covered lifestyle intervention conducted at 22 sites in the united states. Patients with coronary artery disease (nonsmokers; 757 men, 395 women; mean age 61 years) were asked to make changes in diet (10% calories from fat, plant based), engage in moderate exercise (3 hours/week), and practice stress management (1 hour/day). At baseline, 108 patients (43% women) reported mild angina and 174 patients (37% women) reported limiting angina. By 12 weeks, 74% of these patients were angina free, and an additional 9% moved from limiting to mild angina. This improvement in angina was significant for patients with mild and limiting angina at baseline regardless of gender (p <0.01). Significant improvements in cardiac risk factors, quality of life, and lifestyle behaviors were observed, and patients with angina who became angina free by 12 weeks showed the greatest improvements in exercise capacity, depression, and health-related quality of life (p <0.05). In conclusion, the observed improvements in angina in patients making intensive lifestyle changes could drastically reduce their need for revascularization procedures.
Zeng et al. (2013) This study reports outcomes of a Medicare-sponsored demonstration of two intensive lifestyle modification programs (LMPs) in patients with symptomatic coronary heart disease: the Cardiac Wellness Program of the Benson-Henry Mind Body Institute (MBMI) and the Dr Dean Ornish Program for Reversing Heart Disease (Ornish). This multisite demonstration, conducted between 2000 and 2008, enrolled Medicare beneficiaries who had had an acute myocardial infarction or a cardiac procedure within the preceding 12 months or had stable angina pectoris. Health and economic outcomes are compared with matched controls who had received either traditional or no cardiac rehabilitation following similar cardiac events. Each program included a 1-year active intervention of exercise, diet, small-group support, and stress reduction. Medicare claims were used to examine 3-year outcomes. The analysis includes 461 elderly, fee-for-service, Medicare participants and 1,795 controls. Cardiac and non-cardiac hospitalization rates were lower in participants than controls in each program and were statistically significant in MBMI (P < .01). Intensive, year-long LMPs reduced hospitalization rates in elderly beneficiaries with symptomatic coronary heart disease.

Franklin et al. (2014) Unfortunately, many patients as well as the medical community, continue to rely on coronary revascularization procedures and cardioprotective medications as a first-line strategy to stabilize or favorably modify established risk factors and the course of coronary artery disease. However, these therapies do not address the root of the problem, that is, the most proximal risk factors for heart disease, including unhealthy dietary practices, physical inactivity, and cigarette smoking. We argue that more emphasis must be placed on novel approaches to embrace current primary and secondary prevention guidelines, which requires attacking conventional risk factors and their underlying environmental causes. The impact of lifestyle on the risk of cardiovascular disease has been well established in clinical trials, but these results are often overlooked and underemphasized. Considerable data also strongly support the role of lifestyle intervention to improve glucose and insulin homeostasis, as well as physical inactivity and/or low aerobic fitness. Accordingly, intensive diet and exercise interventions can be highly effective in facilitating coronary risk reduction, complementing and enhancing medications, and in some instances, even outperforming drug therapy.

Other Programs
In addition to the Ornish Program for Cardiac outpatient Rehabilitation, CMS has also approved the Pritikin Program and the Benson-Henry program.

The Pritikin Program (Effective August 12, 2010) was designed and adopted by Nathan Pritikin in 1955. The diet was modeled after the diet of the Tarahumara Indians I Mexico, which consisted of 10% fat, 13% protein, 75-80% carbohydrates and provided 15-20 grams per day of crude fiber with only 75mg/day of cholesterol. Over the years, this program evolved into a comprehensive program that is provided in a physician’s office and incorporates a specific diet (i.e. 10-15% of calories from fat, 15-20% from protein, 65-75% from complex carbohydrates), exercise, and counseling lasting 21-26 days.

The Benson-Henry program is a multicomponent intervention program that includes supervised exercise, behavioral interventions such as stress relief, counseling, and is designed to reduce cardiovascular risk and improve health outcomes. Research on this program started about 40 years ago, but coverage with Medicare was effective in May 2014.
CMS based its decision using a peer-reviewed, evidence based approach and determined that the programs accomplished one or more of the following for its patients:

- Positively affected the progression of coronary heart disease
- Reduced the need for coronary bypass surgery
- Reduced the need for percutaneous coronary interventions

The programs also demonstrated through peer-reviewed published research that it accomplished a statistically significant reduction in five or more of the following measures for patients from their levels before cardiac rehabilitation services to after cardiac rehabilitation services:

1. Low-density lipoprotein
2. Triglycerides
3. BMI
4. Systolic BP
5. Diastolic BP
6. The need for cholesterol, BP, and diabetes medications

**Scientific Rationale – Initial**

According to the American Heart Association, within 5 years of an initial myocardial infarction (MI), 15% of men and 22% of women 45 to 64 years of age and 22% of men and women >65 years of age will suffer a recurrent MI or fatal coronary heart disease (CHD). Given this high recurrence rate, preventing secondary cardiac events is an essential part of the care for patients with cardiovascular disease (CVD).

Cardiac rehabilitation (CR)/secondary prevention programs (SSP) are comprehensive long-term programs involving medical evaluation, prescribed exercise, cardiac risk factor modification, education, and counseling. Cardiac rehabilitation programs are designed to limit the physiologic and psychological effects of cardiac illness, reduce the risk for sudden death or re-infarction, control cardiac symptoms, stabilize or reverse the atherosclerotic process, and enhance the psychosocial and vocational status of selected patients.

Comprehensive CR/SPPs consist of baseline patient assessment, nutritional counseling, aggressive risk factor management (i.e., lipids, hypertension, weight, diabetes mellitus, and smoking), psychosocial and vocational counseling, and physical activity counseling and exercise training. A symptom-limited exercise test is administered, establishing the patient’s metabolic equivalents (METs) capacity and identifying high-risk characteristics that require further evaluation or intervention. METs is the total oxygen requirement of the body, with 1 MET equal to 3.5 mL of oxygen consumed per kilogram of body weight per minute. Exercise training improves MET capacity by 10% to 50%, resulting in improved oxygen delivery and extraction by exercising skeletal muscles, thereby decreasing the cardiovascular requirements of exercise and increasing the amount of work that can be done before ischemia occurs. Risk stratification is used to identify patients at risk for death or reinfarction and to provide guidelines for the rehabilitative process. Exercise training is the principle component of CR since it results in increased peak exercise capacity, (usually expressed in METs.) Exercise may involve a stationary bicycle, treadmill, calisthenics, walking, or jogging, and monitoring may include ECG telemetry, depending on a patient's risk status and the intensity of exercise training. Education and counseling concerning risk factor modification are individualized and close communication between the treating physician and cardiac rehabilitation team may promote long-term behavioral change. Patients participating in CR/SPPs are also
prescribed cardioprotective drugs that have evidence-based efficacy for secondary prevention.

Cardiac rehabilitation/secondary prevention programs are generally divided into 3 main phases:

- **Phase 1 (Inpatient CR):** A program that delivers preventive and rehabilitative services to hospitalized patients following an index CVD event, such as an MI/acute coronary syndrome;

- **Phase 2 (Early outpatient CR):** A physician-supervised outpatient program that delivers preventive and rehabilitative services to patients in the outpatient setting early after a CVD event, generally within the first 3 to 6 months after the event but continuing for as much as 1 year after the event;

- **Phase 3 or Phase 4 (Long-term outpatient CR):** A program that provides longer term delivery of preventive and rehabilitative services for patients in the outpatient setting.

Given the significant benefits that CR/SPPs bring to CVD prevention, every recent major evidence-based guideline from the American Heart Association (AHA) and the American College of Cardiology Foundation (ACCF) about the management and prevention of CHD provides a Class I–level recommendation (i.e., procedure/treatment should be performed/administered) for referral to a CR/SPP for those patients with recent myocardial infarction (MI) or acute coronary syndrome (ACS), chronic stable angina, heart failure, or after coronary artery bypass surgery (CABG) or percutaneous coronary intervention (PCI). CR/SPPs are also indicated for those patients after valve surgery or cardiac transplantation.

**ST- Elevation Myocardial infarction (STEMI)**

2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction. A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines recommends exercise-based cardiac rehabilitation/secondary prevention programs for patients with STEMI (Class I, Level of Evidence: B)

Per the guideline, “The objectives of contemporary exercise-based cardiac rehabilitation are to increase functional capacity, decrease or alleviate anginal symptoms, reduce disability, improve quality of life, modify coronary risk factors, and reduce morbidity and mortality rates. Core components include patient assessment; ongoing medical surveillance; nutritional counseling; BP, lipid, and diabetes mellitus management; smoking cessation; psychosocial counseling; physical activity counseling; exercise training; and pharmacological treatment, as appropriate.” The guidelines notes further that among 601,099 U.S. Medicare beneficiaries who were hospitalized for coronary conditions or revascularization procedures, mortality rates were 21% to 34% lower among participants in cardiac rehabilitation programs than among nonparticipants. Unfortunately, they note that cardiac rehabilitation services remain vastly under utilized.

Giallauria et al (2013) evaluated whether long-term exercise-based cardiac rehabilitation started early after STEMI improves myocardial perfusion and left ventricular (LV) function. Forty-six patients with recent STEMI and residual inducible hypoperfusion were randomized into two groups: 25 enrolled in a 6-month outpatient exercise-based cardiac rehabilitation program (group T) and 21 discharged with generic instructions for maintaining physical activity and correct lifestyle (group C). All patients underwent cardiopulmonary exercise test and...
dipyridamole rest gated myocardial perfusion single photon emission computed tomography within 1 week after STEMI and at 6-month follow-up. At follow-up, group T showed an improvement in peak oxygen consumption, oxygen pulse and in the slope of increase in ventilation over carbon dioxide output (all p<0.01) associated with a reduction of stress-induced hypoperfusion (p<0.01) and an improvement in resting and post-stress wall motion score indexes (both p<0.01), resting and post-stress wall thickening score indexes (both p<0.05) and resting and post-stress LV ejection fraction (both p<0.05). On the contrary, no changes in cardiopulmonary indexes, myocardial perfusion and LV function parameters were observed in group C at follow-up. Investigators concluded exercise training started early after STEMI reduces stress-induced hypoperfusion and improves LV function and contractility. Exercise-induced changes in myocardial perfusion and function were associated with the absence of unfavorable LV remodeling and with an improvement of cardiovascular functional capacity.

Lawlor et al (2011) reported that exercise-based CR remains an underused tool for secondary prevention post-MI. In part, this arises from uncertainty regarding the efficacy of CR, particularly with respect to reinfarction, where previous studies have failed to show consistent benefit. The authors undertook a meta-analysis of randomized controlled trials (RCTs) to estimate the effect of CR on cardiovascular outcomes and examine the effect of CR program characteristics on the magnitude of CR benefits. They systematically searched MEDLINE as well as relevant bibliographies to identify all English-language RCTs examining the effects of exercise-based CR among post-MI patients. Data were aggregated using random-effects models. Stratified analyses were conducted to examine the impact of RCT-level characteristics on treatment benefits. 34 RCTs (N = 6,111) were identified. Overall, patients randomized to exercise-based CR had a lower risk of reinfarction (odds ratio [OR] 0.53, 95% CI 0.38-0.76), cardiac mortality (OR 0.64, 95% CI 0.46-0.88), and all-cause mortality (OR 0.74, 95% CI 0.58-0.95). In stratified analyses, treatment effects were consistent regardless of study periods, duration of CR, or time beyond the active intervention. Exercise-based CR had favorable effects on cardiovascular risk factors, including smoking, blood pressure, body weight, and lipid profile. The authors concluded exercise-based CR is associated with reductions in mortality and reinfarction post-MI. The secondary analyses suggest that even shorter CR programs may translate into improved long-term outcomes, although these results need to be confirmed in an RCT.

Haykowsky et al (2011) reported the effects of variations in exercise training on LV remodeling in patients shortly after MI are important but poorly understood. Authors performed a systematic review incorporating meta-analysis using meta-regression. Studies selected were randomized controlled trials of exercise training interventions reporting ejection fraction (EF) and/or ventricular volumes in patients following recent MI (≤ 3 months) post-MI patients involving control groups. Studies were excluded if they were not randomized, did not have a 'usual-care' control (involving no exercise), evaluated a non-exercise intervention, or did not involve human subjects. Non-English studies were also excluded. After screening of 1029 trials, trials were identified that reported EF (12 trials, n = 647), End Systolic Volumes (ESV) (9 trials, n = 475) and End Diastolic Volumes (EDV) (10 trials, n = 512). Meta-regression identified that changes in EF effect size difference decreased as the time between MI and initiation of the exercise program lengthened, and increased as the duration of the program increased (Q = 25.48, df = 2, p < 0.01, R2 = 0.76). Greater reductions in ESV and EDV (as indicated by effect size decreases) occurred with earlier initiation of exercise training and with longer training durations (ESV: Q = 23.89, df = 2, p < 0.05, R2 = 0.79; EDV: Q = 27.42, df = 2, p < 0.01, R2 = 0.83). Differences remained following sensitivity analysis. Each week that exercise was delayed required an additional month of training to achieve the same level of benefit.
on LV remodeling. The reviewers concluded exercise training has beneficial effects on LV remodeling in clinically stable post-MI patients with greatest benefits occurring when training starts earlier following MI (from one week) and lasts longer than 3 months.

Antonakoudis et al (2006) investigated the significance of CR on Health Related Quality of Life (HRQoL) in post acute MI patients. A total number off 110 individuals divided in 3 groups was included in the study. Group A consisted of 60 post-acute MI patients participating in a CR program. It was a multidisciplinary rehabilitative approach including supervised bike exercise, with parallel education, counselling, psychological and social support, performed 3 times per week for 2 months after acute MI. Group B consisted of 40 post-acute MI patients not participating in any CR program while the control group C consisted of 10 apparently healthy people. HRQoL was evaluated by the Velasco-Del Barrio questionnaire. Questions on this questionnaire are referred to 9 categories (health, sleep and rest, emotional behavior, concerns for the future, mobility, social interaction, alertness behavior, communication, work and leisure time). A 5-point scale (1=all of the time, 5=none of the time) and a special (1 to 8) coefficient for each parameter were used for the evaluation of each parameter. The highest score of 220 indicates the poorest QL.

Results. Group A patients had better score of HRQoL as compared to Group B (94±3 vs 114±3, p<0.001) and slightly worse than Group C patients (94±4 vs 69±3, p<0.01). Significant difference was found among Group A and B patients regarding the most important evaluated parameters such as symptoms (17±6.8 vs 22±6.5, p<0.001) and social behavior (21±4.2 vs 23±5.5, p<0.0001). Investigators concluded that participation in a multidisciplinary CR program significantly improves HRQoL in post acute MI patients. All these patients must urged to take part in such programs.

Unstable Angina/Non ST-elevation Myocardial Infarction (NSTEMI)
2012 ACCF/AHA Focused Update Incorporated into the ACCF/AHA 2007 Guidelines for the Management of Patients With Unstable Angina (UA)/Non–ST-Elevation Myocardial Infarction (NSTEMI) recommend cardiac rehabilitation/secondary prevention programs are recommended for patients with UA/NSTEMI, particularly those with multiple modifiable risk factors and/or those moderate- to high-risk patients in whom supervised exercise training is particularly warranted. (Class I, Level of Evidence: B.) The guidelines note that enrollment in a cardiac rehabilitation program after discharge can enhance patient education and compliance with the medical regimen and assist with the implementation of a regular exercise program. Exercise training can generally begin within 1 to 2 weeks after UA/NSTEMI treated with PCI or CABG to relieve ischemia.

Coronary Artery Bypass Graft Surgery (CABG)
2011 ACCF/AHA guideline for coronary artery bypass graft surgery: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines recommends cardiac rehabilitation is recommended for all eligible patients after CABG (Class I, level of evidence B)

Per the guideline, “Beginning 4 to 8 weeks after CABG, 3-times weekly education and exercise sessions for 3 months are associated with a 35% increase in exercise tolerance (p=0.0001), a slight (2%) (p=0.05) increase in high-density lipoprotein cholesterol, and a 6% reduction in body fat (p=0.002). Exercise training is a valuable adjunct to dietary modification of fat and total caloric intake in maximizing the reduction of body fat while minimizing the reduction of lean body mass. Aerobic training improves volume of maximum oxygen consumption at 6 months compared with moderate continuous training (p=0.001).”
Grifo et al (2013) investigated the impact of a CR program on lifestyle, risk factors and medication modifications and analyze predictors of poor behavioral changes and events in patients after CABG or PCI. This was a multicenter (n=62), prospective, longitudinal survey in post-CABG or -PCI consecutive patients after a comprehensive CR program. Cardiac risk factors, lifestyle habits, medication and 1 year cardiovascular events were collected. Logistic regression analyzed the association between risk factors, events and predictors of non-adherence to treatment and lifestyle. At 1 year, of the 1262 patients (66 ± 10 years, CABG 69%, PCI 31%), 94% were taking antiplatelet agents (vs. 91.8% at CR admission and 91.7% at CR discharge, p=ns), 87% statins (vs. 67.5%, p<.0001, and 86.3%, p=ns), 80.7% beta-blockers (vs. 67.4%, p<.0001, and 88.8%, p=ns), and 81.1% ACE inhibitors (vs. 57.5% p<.0001, and 77.7%, p=ns). 89.9% of the patients showed good adherence to treatment, 72% adhered to diet and 51% to exercise recommendations; 74% of smokers stopped smoking. Younger age was predictive of smoking resumption (OR 8.9, CI 3.5-22.8). Pre-event sedentary lifestyle (OR 3.3, CI 1.3-8.7) was predictive of poor diet. Older patients with comorbidity (OR 3.1; CI, 1.8-5.2) tended to persist in sedentary lifestyle and discontinue therapy and diet recommendations. Age, diabetes, smoking and PCI indication were predictors of recurrent CV events which occurred in 142 patients. Investigators concluded participation in CR results in excellent treatment after revascularization, as well as a good lifestyle and medication adherence at 1 year and provides further confirmation of the benefit of secondary prevention. Several clinical characteristics may predict poor behavioral changes.

**Percutaneous Coronary Intervention (PCI)**

2011 ACCF/AHA/SCAI guideline for percutaneous coronary artery intervention. A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions recommends a medically supervised exercise programs (cardiac rehabilitation) for individuals after PCI, particularly for moderate- to high-risk patients for whom supervised exercise training is warranted. (Class I; Level of Evidence: A)

Per the guideline, “Participation in cardiac rehabilitation is associated with significant reductions in all-cause mortality (OR: 0.80, 95% CI: 0.68 to 0.93) and cardiac mortality. Reports from community-based surveys, which in general enroll older and higher-risk patients than clinical trials, have confirmed that participation in comprehensive rehabilitation is independently associated with a reduction in recurrent MI and reduced mortality. Cardiac rehabilitation is also associated with improvements in exercise tolerance, cardiac symptoms, lipid levels, cigarette smoking cessation rates (in conjunction with a smoking cessation program), stress levels, improved medical regimen compliance, and improved psychosocial well-being.”

For patients entering a formal cardiac rehabilitation program after PCI, treadmill exercise testing is reasonable. (Class IIa recommendation; Level of evidence C)

Per the guideline, “Treadmill exercise testing before cardiac rehabilitation provides information about peak exercise capacity and heart rate, helping to stratify patients for the level of supervision during training, and seems reasonable for this purpose; nuclear imaging to assess ischemia in this context usually adds little.”

Borowicz-Bienkowska et al (2013) sought to determine whether short-term CR, including dietary counseling, had an impact on changing eating habits in patients after ACS, treated with primary PCI. The controlled, prospective, nonrandomized study was performed on 44 patients, early following ACS/PCI, who underwent 2- to 3-week inpatient CR with dietary counseling and compared to 18 patients who did
not participate in CR. An analysis of the daily diet composition was performed at baseline, at 3 months post-ACS, and at 1 year post-ACS. In the CR group, comparing baseline with 3 months post-ACS, daily calorie intake was significantly reduced from a mean ± SD of 2260 ± 525 kcal to 2037 ± 514 kcal (P < .05), and daily cholesterol intake from 509 ± 237 to 394 ± 199 mg (P < .05). The daily energy intake of saturated fatty acids was also significantly reduced from 13.6% at baseline to 12.2 ± 4.5% at 3 months and further reduced at 1 year post-ACS to 10.2 ± 4.3% (P < .05). Although both groups exhibited increased body mass index, the increase was significantly greater in the nonrehabilitation group than in the CR group at 1 year post-ACS (2.61 ± 2.23 vs 0.86 ± 1.67 kg/m², respectively, P < .001). Investigators concluded the analysis suggests that a short-term CR program following ACS, which includes educational meetings on dietary prevention of atherosclerosis, may result in some favorable and lasting modifications of eating habits of post-ACS patients.

Golabchi et al (2012) examined the effects of an 8-week CR on left ventricular diastolic function in a randomized, clinical trial including 29 men with ST elevation MI who had received reperfusion therapy, i.e. CABG or PCI. They were randomized to a training group (n = 15; mean age: 54.2 ± 9.04 years old) and a control group (n = 14; mean age: 51.71 ± 6.98 years old). Patients in the training group performed an 8-week CR with an intensity of 60–85% of maximum heart rate. Exercise sessions lasted 60–90 minutes and were held three times a week. At the start and end of the study, all patients performed symptom-limited exercise test based on Naughton treadmill protocol. Pulsed-wave Doppler echocardiography was also used to determine peak velocity of early (E) and late (A) waves, E/A ratios, and the deceleration time of E (DT). Left ventricular diastolic indices (E, A, E/A ratio, DT) did not change significantly after the CR. Compared to baseline, patients in the training group had significant improvements in functional capacity (8.30 ± 1.30 vs. 9.7 ± 1.7) and maximum heart rate (118.50 ± 24.48 vs. 126.85 ± 22.75). Moreover, resting heart rate of the training group was significantly better than the control group at the end of the study (75.36 ± 7.94 vs. 79.80 ± 7.67; P < 0.001). Investigators concluded an 8-week CR in post-MI patients revascularized with PCI or CABG led to improved exercise capacity. However, the CR failed to enhance diastolic function.

**Stable Ischemic Heart Disease (SIHD)**

2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guidelines for the diagnosis and management of patients with stable ischemic heart disease recommends medically supervised programs (cardiac rehabilitation) and physician-directed, home-based programs for at-risk individuals patients at first diagnosis (Class I, Level of Evidence: A).

Per the guideline, multiple controlled clinical trials have examined the benefits of exercise training and cardiac rehabilitation in patients with IHD. Most of these studies have been relatively small, but in aggregate they demonstrate that regular exercise reduces mortality in patients with IHD. Many of the studies demonstrating the efficacy of exercise-based cardiac rehabilitation enrolled patients after an AMI or coronary revascularization procedure. Clear benefits of exercise training also have been shown in patients with stable angina. Controlled trials consistently have demonstrated an improvement in functional capacity and a delay in the onset of ischemia in anginal patients who complete an exercise training program. Exercise-based cardiac rehabilitation could also reduce subjective evidence of ischemia and could ameliorate symptoms.

The guidelines also note, it seems prudent, however, that patients at high risk of cardiac complications (i.e., those with a history of multiple MIs or cardiac arrest, New
York Heart Association functional class III or IV or exercise capacity <6 metabolic equivalents (METs), or significant exercise-induced ischemia on treadmill testing) participate in a medically supervised program for at least 8 to 12 weeks to establish the safety of the prescribed exercise regimen.

**Chronic Heart Failure**

Chronic heart failure (CHF) is highly prevalent in older individuals and is a major cause of morbidity, mortality, hospitalizations, and disability. Patients with heart failure (HF) often have limited exercise capacity because of dyspnea and fatigue. Studies have demonstrated that significant biochemical and functional abnormalities in skeletal muscle are present in patients with HF and play a large role in the exercise intolerance. Inactivity is in part responsible, leading to muscle atrophy. In addition, skeletal muscle utilizes high-energy phosphates in an inefficient manner; as a result, lactic acid accumulates at a more rapid rate than in normal controls, contributing to muscle fatigue and limited exercise capacity. Skeletal muscle dysfunction can also involve the respiratory muscles, which may contribute to fatigue and dyspnea on exertion. These biochemical and functional abnormalities, when added to deconditioning, can result in even greater impact on physical function. The importance of skeletal muscle dysfunction provides part of the rationale for the use of cardiac rehabilitation in patients with HF.

Numerous cardiac rehabilitation studies have demonstrated the safety and efficacy of exercise training in patients with HF. These trials have shown that cardiac rehabilitation can produce improvement in maximal exercise tolerance, as measured by an increase in exercise time, peak oxygen uptake (VO2 peak), or New York Heart Association (NYHA) functional class after one to six months of exercise training. Meta-analyses show that cardiac rehabilitation reduces mortality; improves functional capacity, exercise duration, and HRQOL and reduces hospitalizations. Other benefits include improved endothelial function, blunted catecholamine spillover, increased peripheral oxygen extraction, and reduced hospital admission.

2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines recommend:

- Exercise training (or regular physical activity) is recommended as safe and effective for patients with heart failure (HF) who are able to participate to improve functional status (Class I, Level of Evidence: A)
- Cardiac rehabilitation can be useful in clinically stable patients with heart failure (HF) to improve functional capacity, exercise duration, HRQOL, and mortality. (Class IIa, Level of Evidence: B)

In February 2014, the Centers for Medicare & Medicaid Services (CMS) issued a decision memo stating the evidence is sufficient to expand coverage for cardiac rehabilitation services to beneficiaries with stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35% or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least six weeks. Stable patients are defined as patients who have not had recent (≤6 weeks) or planned (≤6 months) major cardiovascular hospitalizations or procedures.

Edelmann et al (2011) sought to determine whether structured exercise training (ET) improves maximal exercise capacity, left ventricular diastolic function, and quality of life (QoL) in patients with heart failure with preserved ejection fraction (HFpEF).
A total of 64 patients (age 65±7 years, 56% female) with HFpEF were prospectively randomized (2:1) to supervised endurance/resistance training in addition to usual care (ET, n = 44) or to usual care alone (UC) (n = 20). The primary endpoint was the change in peak Vo(2) after 3 months. Secondary endpoints included effects on cardiac structure, diastolic function, and QoL. Peak Vo(2) increased (16.1±4.9 ml/min/kg to 18.7±5.4 ml/min/kg; p<0.001) with ET and remained unchanged (16.7±4.7 ml/min/kg to 16.0±6.0 ml/min/kg; p = NS) with UC. The mean benefit of ET was 3.3 ml/min/kg (95% confidence interval [CI]: 1.8 to 4.8, p<0.001). E/e' (mean difference of changes: -3.2, 95% CI: -4.3 to -2.1, p<0.001) and left atrial volume index (milliliters per square meter) decreased with ET and remained unchanged with UC (-4.0, 95% CI: -5.9 to -2.2, p<0.001). The physical functioning score (36-Item Short-Form Health Survey) improved with ET and remained unchanged with UC (15, 95% CI: 7 to 24, p<0.001). The ET-induced decrease of E/e' was associated with 38% gain in peak Vo(2) and 50% of the improvement in physical functioning score. Investigators concluded exercise training improves exercise capacity and physical dimensions of QoL in HFpEF. This benefit is associated with atrial reverse remodeling and improved left ventricular diastolic function. (Exercise Training in Diastolic Heart Failure-Pilot Study: A Prospective, Randomised, Controlled Study to Determine the Effects of Physical Training on Exercise Capacity and Quality of Life; ISRCTN42524037).

Whellan et al (2011) performed a post hoc analysis of the HF-ACTION cohort that explores the primary and secondary results of the HF-ACTION study by etiology and severity of illness. HF-ACTION randomized stable outpatients with reduced LV function and HF symptoms to either supervised exercise training plus usual care or to usual care alone. The primary outcome was all-cause mortality or all-cause hospitalization; secondary outcomes included all-cause mortality, cardiovascular mortality or cardiovascular hospitalization, and cardiovascular mortality or HF hospitalization. The interaction between treatment and risk variable, etiology or severity as determined by risk score, New York Heart Association class, and duration of cardiopulmonary exercise test was examined in a Cox proportional hazards model for all clinical end points. There was no interaction between etiology and treatment for the primary outcome (P = .73), cardiovascular (CV) mortality or CV hospitalization (P = .59), or CV mortality or HF hospitalization (P = .07). There was a significant interaction between etiology and treatment for the outcome of mortality (P = .03), but the interaction was no longer significant when adjusted for HF-ACTION adjustment model predictors (P = .08). There was no significant interaction between treatment effect and severity, except a significant interaction between cardiopulmonary exercise duration and training was identified for the primary outcome of all-cause mortality or all-cause hospitalization. Investigators concluded consideration of symptomatic (New York Heart Association classes II to IV) patients with HF with reduced LV function for participation in an exercise training program should be made independent of the cause of HF or the severity of the symptoms.

Kitzman et al (2010) reports HFPEF is the most common form of HF in the older population. Exercise intolerance is the primary chronic symptom in patients with HFPEF and is a strong determinant of their reduced quality of life (QOL). ET improves exercise intolerance and QOL in patients with HF with reduced EF. However, the effect of ET in HFPEF has not been examined in a randomized controlled trial. This 16-week investigation was a randomized, attention-controlled, single-blind study of medically supervised ET (3 days per week) on exercise intolerance and QOL in 53 elderly patients (mean age, 70±6 years; range, 60 to 82 years; women, 46) with isolated HFPEF (EF≥50% and no significant coronary, valvular, or pulmonary disease). Attention controls received biweekly follow-up telephone calls. Forty-six patients completed the study (24 ET, 22 controls). Attendance at exercise sessions in the ET group was excellent (88%; range, 64% to 100%). There were no trial-related
adverse events. The primary outcome of peak exercise oxygen uptake increased significantly in the ET group compared to the control group (13.8±2.5 to 16.1±2.6 mL/kg per minute [change, 2.3±2.2 mL/kg per minute] versus 12.8±2.6 to 12.5±3.4 mL/kg per minute [change, -0.3±2.1 mL/kg per minute]; P=0.0002). There were significant improvements in peak power output, exercise time, 6-minute walk distance, and ventilatory anaerobic threshold (all P<0.002). There was improvement in the physical QOL score (P=0.03) but not in the total score (P=0.11). Investigators concluded ET improves peak and submaximal exercise capacity in older patients with HFPEF.

O'Connor et al (2010) sought to test the efficacy and safety of exercise training among patients with heart failure in a multicenter, randomized controlled trial of 2331 medically stable outpatients with heart failure and reduced ejection fraction. Participants in Heart Failure: A Controlled Trial Investigating Outcomes of Exercise Training (HF-ACTION) were randomized from April 2003 through February 2007 at 82 centers within the United States, Canada, and France; median follow-up was 30 months. Participants were randomized to usual care plus aerobic exercise training, consisting of 36 supervised sessions followed by home-based training, or usual care alone. Composite primary end point of all-cause mortality or hospitalization and prespecified secondary end points of all-cause mortality, cardiovascular mortality or cardiovascular hospitalization, and cardiovascular mortality or heart failure hospitalization. The median age was 59 years, 28% were women, and 37% had New York Heart Association class III or IV symptoms. Heart failure etiology was ischemic in 51%, and median left ventricular ejection fraction was 25%. Exercise adherence decreased from a median of 95 minutes per week during months 4 through 6 of follow-up to 74 minutes per week during months 10 through 12. A total of 759 patients (65%) in the exercise training group died or were hospitalized compared with 796 patients (68%) in the usual care group (hazard ratio [HR], 0.93 [95% confidence interval {CI}, 0.84-1.02]; P = .13). There were nonsignificant reductions in the exercise training group for mortality (189 patients [16%]in the exercise training group vs 198 patients [17%]in the usual care group; HR, 0.96 [95% CI, 0.79-1.17]; P = .70), cardiovascular mortality or cardiovascular hospitalization (632 [55%]in the exercise training group vs 677 [58%]in the usual care group; HR, 0.92 [95% CI, 0.83-1.03]; P = .14), and cardiovascular mortality or heart failure hospitalization (344 [30%]in the exercise training group vs 393 [34%]in the usual care group; HR, 0.87 [95% CI, 0.75-1.00]; P = .06). In prespecified supplementary analyses adjusting for highly prognostic baseline characteristics, the HRs were 0.89 (95% CI, 0.81-0.99; P = .03) for all-cause mortality or hospitalization, 0.91 (95% CI, 0.82-1.01; P = .09) for cardiovascular mortality or cardiovascular hospitalization, and 0.85 (95% CI, 0.74-0.99; P = .03) for cardiovascular mortality or heart failure hospitalization. Other adverse events were similar between the groups. Investigators concluded in the protocol-specified primary analysis, exercise training resulted in nonsignificant reductions in the primary end point of all-cause mortality or hospitalization and in key secondary clinical end points. After adjustment for highly prognostic predictors of the primary end point, exercise training was associated with modest significant reductions for both all-cause mortality or hospitalization and cardiovascular mortality or heart failure hospitalization. (TRIAL REGISTRATION: clinicaltrials.gov Identifier: NCT00047437.)

A Cochrane review reported by Davies et al (2010) sought to determine the effect of exercise training on clinical events and health-related quality of life (HRQoL) of patients with systolic heart failure. Electronic databases including Medline, EMBASE, and Cochrane Library up to January 2008 were reviewed to identify RCTs comparing exercise training and usual care with a minimum follow-up of 6 months. Nineteen RCTs were included with a total of 3647 patients, the majority of whom were male, low-to-medium risk, and New York Heart Association class II-III with a left
ventricular ejection fraction of <40%. There was no significant difference between exercise and control in short-term (<or=12 months) or longer-term all-cause mortality or overall hospital admissions. Heart failure-related hospitalizations were lower [relative risk: 0.72, 95% confidence interval (CI): 0.52-0.99] and HRQoL improved (standardized mean difference: -0.63, 95% CI: -0.80 to -0.37) with exercise therapy. Any effect of cardiac exercise training on total mortality and HRQoL was independent of degree of left ventricular dysfunction, type of cardiac rehabilitation, dose of exercise intervention, length of follow-up, trial quality, and trial publication date. Reviewers concluded compared with usual care, in selected heart failure patients, exercise training reduces heart failure-related hospitalizations and results in clinically important improvements in HRQoL. High-quality RCT and cost-effectiveness evidence is needed for the effect of exercise training in community-based settings and in more severe heart failure patients, elderly people, and women.

**Transplant**

Although data are limited, cardiac rehabilitation may provide benefit both early and later after transplant. Long term improvement is limited, which may be due to the effects of aging, cardiac denervation, transplant therapy, and prior heart failure.

Hsu et al (2011) investigated the effect of an early postoperative outpatient cardiac rehabilitation program to health-related quality of life among heart transplantation recipients (HTR) and patients with CABG surgery. The study included 45 clinically stable HTR (age: 47 ± 14 years; 36 men, 9 women) and 34 patients with CABG (age: 57.2 ± 12.5 years; 27 men, 7 women). HTR started rehabilitation 70 ± 33 days after transplantation; patients with CABG started training 36 ± 18 days after surgery. Patients participated in a 12-week supervised exercise training program three times per week. Each training session comprised 10 minutes of warm-up, 25 to 30 minutes of cycling or treadmill walking, and 10 minutes of cool down. The exercise intensity was set at 50% to 80% of peak oxygen uptake (V̇O(2peak)) according to the patient’s condition. The health-related quality of life of subjects was evaluated by the Medical Outcomes Trust 36-item health survey (SF-36) at baseline and upon the completion of rehabilitation. At baseline, the HTR group showed lower V̇O(2peak) than the CABG group, but the health-related quality of life was similar between the two groups. After training, both groups exhibited an increase of 3.6 mL·kg(-1)·min(-1) in V̇O(2peak) and improvement of physical component in health-related quality of life. The HTR group showed a significant increase of SF-36 scores in physical functioning (59.7 ± 18.9 to 77.0 ± 14.0), physical role (21.1 ± 34.1 to 38.3 ± 37.9), bodily pain (57.4 ± 24.3 to 73.6 ± 21.5), social functioning (63.6 ± 23.4 to 72.8 ± 22.1), emotional role (59.2 ± 43.7 to 76.3 ± 37.4), and mental health (67.1 ± 17.9 to 73.4 ± 14.6). The CABG group only exhibited increased scores in physical functioning (60.0 ± 22.9 to 73.4 ± 18.0), physical role (19.1 ± 24.9 to 27.9 ± 38.3), bodily pain (57.1 ± 20.0 to 70.3 ± 16.1), and social functioning (54.0 ± 21.3 to 69.9 ± 21.1). Investigators concluded early postoperative cardiac rehabilitation significantly improved physical capacity and quality of life among heart transplant recipients and patients with CABG. Additionally, HTR showed greater improvement in health-related quality of life than patients with CABG regardless of lower physical capacity.

Hermann et al (2011) examined whether high intensity aerobic exercise improves peak oxygen uptake (VO(2 peak) ) and endothelial function in heart transplant (HT) recipients. Twenty-seven long-term HT recipients were randomized to either 8-weeks high intensity aerobic exercise or no training. Flow mediated dilation of the brachial artery (FMD) was measured by ultrasound and VO(2 peak) by the analysis of expired air. Blood pressure and biomarkers were measured before and after 8 weeks. VO(2 peak) increased significantly in the exercise group (VO(2 peak) 23.9 ± 1.79 to 28.3
± 1.63 mL/kg/min compared to controls (VO2 peak) 24.6 ± 1.38 to 23.4 ± 1.58, p < 0.001 exercise vs. control). FMD increased in the exercise group compared to controls (8.3 ± 1.1% to 11.4 ± 1.2% vs. 5.6 ± 1.0% to 5.3 ± 1.7%, p = 0.024). No increase in nitroglycerin-induced vasodilation was observed. Systolic blood pressure fell in the exercise group (142 ±4.2 mmHg to127 ± 3.4 mmHg, p = 0.01) and was unchanged in controls (141 ± 4.2 mmHg to 142 ±6.4 mmHg, NS). High intensity aerobic exercise reduces systolic blood pressure and improves endothelial function in HT recipients.

Haykowsky et al (2009) examined the effects of 12 weeks of supervised aerobic and strength training (SET) versus no-training (NT) on peak aerobic power (VO2peak), submaximal exercise LV systolic function, peripheral vascular function, lean tissue mass and maximal strength in clinically stable heart transplant recipients (HTR). Forty-three HTR were randomly assigned to 12 weeks of SET (n = 22; age: 57 +/- 10 years; time posttransplant: 5.4 +/- 4.9 years) or NT (n = 21; age: 59 +/- 11 years; time posttransplant: 4.4 +/- 3.3 years). The change in VO2peak (3.11 mL/kg/min, 95% CI: 1.2-5.0 mL/kg/min), leg and total lean tissue mass (0.78 kg, 95% CI: 0.31-1.3 kg and 1.34 kg, 95% CI: 0.34-2.3 kg, respectively), chest-press (10.4 kg, 95% CI: 5.2-15.5 kg) and leg-press strength (34.7 kg, 95% CI: 3.7-65.6 kg) were significantly higher after SET versus NT. No significant change was found for submaximal exercise LV systolic function or brachial artery endothelial-dependent or -independent vasodilation. Supervised exercise training is an effective intervention to improve VO2peak, lean tissue mass and muscle strength in HTR. This training regimen did not improve exercise LV systolic function or brachial artery endothelial function.

**Left ventricular Assist Device**

Alsara et al (2014) report that published studies have shown that left ventricular assist device (LVAD) implantation, by itself, improves exercise tolerance to the point where it is comparable to those with mild heart failure. The improvement in exercise capacity is maximally achieved 12 weeks after LVAD therapy and can continue even after explantation of the device. This effect varies, depending on the type of LVAD and exercise training. The available data in the literature on safety and benefits of exercise training in patients after LVAD implantation are limited, but the data that are available suggest that training trends to be safe and have an impact on exercise capacity in LVAD patients. Although no studies were identified on the role of cardiac rehabilitation programs in the management of LVAD patients, it appears that cardiac rehabilitation programs offer an ideal setting for the provision of supervised exercise training in this patient group.

Karapolat H et al (2013) assessed the effects of CR on the functional capacity, pulmonary functions, quality of life, and psychological state of patients who had HF, heart transplantation (HTx), or a LVAD. An 8-week exercise program was undertaken by 46 patients diagnosed with end-stage heart failure, 40 of whom had a heart transplantation and 11 were implanted with an LVAD. The patients' functionality was assessed with a maximal oxygen consumption test (pVO2), their psychological state with the Beck Depression Inventory (BDI) and State-Trait Anxiety Inventory (STAI), their quality of life (QOL) with the Short Form 36 (SF 36), and their pulmonary condition with pulmonary function tests (PFTs). A significant improvement was observed in all forced vital capacity (%), forced expiratory volume in 1 second (%), pVO2, BDI, and most of the subscores of the SF 36 scores at the end of the exercise, compared with the pre-exercise period (P < .05). The intergroup evaluations showed no significant differences among the 3 groups in terms of all assessed changes (P > .05). Investigators concluded an 8-week supervised exercise program was observed to improve functional capacity, PFT, QOL, and depression.
among patients who had HF, HTx, or LVAD. Supervised exercise should be recommended for every patient included in a heart transplant program.

Hayes et al (2012) reported a paucity of studies has examined the effect of exercise training after LVAD implantation. Previous research has demonstrated that insertion of the LVAD alone improves exercise capacity and quality of life (QOL). This study investigated whether supervised exercise training results in a further improvement. This prospective, randomized controlled trial with concealed allocation, assessor blinding, and intention-to-treat analysis investigated the effect of exercise training on exercise capacity and QOL in 14 patients who underwent LVAD insertion as a bridge to heart transplantation. Exercise training consisted of 8 weeks of gym-based aerobic and strengthening exercises 3 times a week, with a progressive mobilization program, compared with the control group that completed mobilization alone.

Exercise capacity was measured before and after the intervention using maximal cardiopulmonary exercise testing and 6-minute walk distance (6MWD). QOL was measured using the Short Form 36-item assessment. No adverse events were reported. There was a trend toward greater improvement in peak oxygen consumption (Vo(2)), 6MWD, and QOL in the exercise group (n = 7) compared with the control group (n = 7); however, no significant between-group difference was detected for improvements in peak Vo(2) [mean difference (exercise--control)] of 2.96 ml/kg/min (95% confidence interval, -1.04 to 6.97), 6MWD at 54 meters (-51 to 159 meters), and QOL scores over time (p > 0.05). Investigators concluded exercise training is feasible and safe in patients with a LVAD. Trends toward greater improvement in exercise capacity and QOL after exercise training warrant further investigation in a larger trial.

**Peripheral Artery Disease**

Peripheral Artery Disease (PAD) accelerates functional decline leading to physical disability. Individuals with PAD frequently have coexistent coronary artery disease. Patients with PAD have markedly reduced health-related quality of life and a higher prevalence of depression, which is largely related to leg symptoms. Diminished physical activity in daily life predicts higher overall mortality in PAD. Supervised exercise therapy combined with comprehensive secondary prevention has the potential to benefit patients with PAD by preserving or improving functional capacity and reducing cardiovascular events. The goals of comprehensive prevention strategies, including exercise, include: reduction of limb symptoms; improve exercise capacity and prevent or lessen physical disability; and to decrease the occurrence of cardiovascular events.

A report of the American College of Cardiology Foundation/American Heart Association Task Force Practice Guidelines, Management of Patients with Peripheral Artery Disease, Compilation of 2005 and 2011 ACCF/AHA guideline recommendations, make the following recommendations:

**Exercise and Lower Extremity PAD Rehabilitation**

CLASS I
1. A program of supervised exercise training is recommended as an initial treatment modality for patients with intermittent claudication. (Level of Evidence: A)

2. Supervised exercise training should be performed for a minimum of 30 to 45 minutes, in sessions performed at least 3 times per week for a minimum of 12 weeks. (Level of Evidence: A)

CLASS IIb
1. The usefulness of unsupervised exercise programs is not well established as an effective initial treatment modality for patients with intermittent claudication. (Level of Evidence: B)

The European Society of Cardiology (ESC) Guidelines on the diagnosis and treatment of peripheral artery disease, state the following regarding exercise therapy reported:

"In patients with lower extremity peripheral artery disease, training therapy is effective in improving symptoms and increasing exercise capacity. In a meta-analysis (Watson et al) including data from 1200 participants with stable leg pain, compared with usual care or placebo, exercise significantly improved maximal walking time, with an overall improvement in walking ability of about 50–200%. Walking distances were also significantly improved. Improvements were seen for up to 2 years. Best evidence comes from studies with a short period of regular and intensive training under supervised conditions. In a meta-analysis of eight trials collecting data from only 319 patients, supervised exercise therapy showed statistically significant and clinically relevant differences in improvement of maximal treadmill walking distance compared with non-supervised exercise therapy regimens (+150 m on average). In general, the training program lasts for 3 months, with three sessions per week. The training intensity on the treadmill increases over time, with a session duration of 30–60 min. Of note, in a small randomized trial (Hodges et al) comparing supervised exercise therapy with usual care, while no significant changes in peak cardiovascular measurements were noted after 12 weeks of exercise, patients under supervised exercise therapy were more efficient in meeting the circulation and ventilation demands of exercise."

An updated Cochrane review reported by Fokkenrood et al (2013), the main objective was to provide an accurate overview of studies evaluating the effects of supervised versus non-supervised exercise therapy on maximal walking time or distance on a treadmill for people with intermittent claudication. A total of 14 studies involving a total of 1002 male and female participants with PAD were included in this review. Follow-up ranged from six weeks to 12 months. In general, supervised exercise regimens consisted of three exercise sessions per week. All trials used a treadmill walking test as one of the outcome measures. The overall quality of the included trials was moderate to good, although some trials were small with respect to the number of participants, ranging from 20 to 304. Supervised exercise therapy (SET) showed statistically significant improvement in maximal treadmill walking distance compared with non-supervised exercise therapy regimens, with an overall effect size of 0.69 (95% confidence interval (CI) 0.51 to 0.86) and 0.48 (95% CI 0.32 to 0.64) at three and six months, respectively. This translates to an increase in walking distance of approximately 180 meters that favored the supervised group. SET was still beneficial for maximal and pain-free walking distances at 12 months, but it did not have a significant effect on quality of life parameters. Reviewers concluded SET has statistically significant benefit on treadmill walking distance (maximal and pain-free) compared with non-supervised regimens. However, the clinical relevance of this has not been demonstrated definitively; additional studies are required that focus on quality of life or other disease-specific functional outcomes, such as walking behavior, patient satisfaction, costs, and long-term follow-up. Professionals in the vascular field should make SET available for all patients with intermittent claudication.

Guidon and McGee (2013) assessed the one-year effects of participation in a 12-week supervised exercise program on functional capacity and QoL for PAD patients. Patients were randomly allocated to a control (n = 16) or an exercise (n = 28) group. Data regarding functional capacity (Walking Impairment Questionnaire WIQ), disease-specific QoL (Intermittent Claudication Questionnaire ICQ) and generic QoL
(SF-36) were collected at baseline, 12 weeks and 1 year. At 12 weeks, there was a trend towards improved QoL in both groups, with a tendency for greater improvement in the exercise group (p = 0.066) and a trend towards improved functional capacity (WIQ Stair-climbing p = 0.093) in the exercise group. At 1 year, ICQ scores in the exercise group were considerably better than those in the control group (p = 0.058), reflecting improved QoL and maintenance of benefits. Investigators concluded participation in a supervised exercise program results in improvements in functional capacity and QoL at 1 year post-participation.

Gardner et al (2012) sought to determine whether an optimal exercise program length exists to efficaciously change claudication onset time (COT) and peak walking time (PWT) in patients with peripheral artery disease and claudication in a prospective, randomized controlled clinical trial. The study randomized 142 patients to supervised exercise (n = 106) or a usual care control group (n = 36), with 80 completing the exercise program and 27 completing the control intervention. The exercise program consisted of intermittent walking to nearly maximal claudication pain 3 days per week. COT and PWT were the primary outcomes obtained from a treadmill exercise test at baseline and bimonthly during the study. After exercise, changes in COT (P < .001) and PWT (P < .001) were consistently greater than changes after the control intervention. In the exercise program, COT and PWT increased from baseline to month 2 (P < .05) and from months 2 to 4 (P < .05) but did not significantly change from months 4 to 6 (P > .05). When changes were expressed per mile walked during the first 2 months, middle 2 months, and final 2 months of exercise, COT and PWT only increased during the first 2 months (P < .05). Investigators concluded exercise-mediated gains in COT and PWT occur rapidly within the first 2 months of exercise rehabilitation and are maintained with further training. The clinical significance is that a relatively short 2-month exercise program may be preferred to a longer program to treat claudication because adherence is higher, costs associated with personnel and use of facilities are lower per patient, and more patients can be trained for a given amount of personnel time and resource utilization.

Murphy et al (2012) reported claudication is a common and disabling symptom of peripheral artery disease that can be treated with medication, supervised exercise (SE), or stent revascularization (ST). Investigators randomly assigned 111 patients with aortoiliac peripheral artery disease to receive 1 of 3 treatments: optimal medical care (OMC), OMC plus SE, or OMC plus ST. The primary end point was the change in peak walking time on a graded treadmill test at 6 months compared with baseline. Secondary end points included free-living step activity, quality of life with the Walking Impairment Questionnaire, Peripheral Artery Questionnaire, Medical Outcomes Study 12-Item Short Form, and cardiovascular risk factors. At the 6-month follow-up, change in peak walking time (the primary end point) was greatest for SE, intermediate for ST, and least with OMC (mean change versus baseline, 5.8±4.6, 3.7±4.9, and 1.2±2.6 minutes, respectively; P<0.001 for the comparison of SE versus OMC, P=0.02 for ST versus OMC, and P=0.04 for SE versus ST). Although disease-specific quality of life as assessed by the Walking Impairment Questionnaire and Peripheral Artery Questionnaire also improved with both SE and ST compared with OMC, for most scales, the extent of improvement was greater with ST than SE. Free-living step activity increased more with ST than with either SE or OMC alone (114±274 versus 73±139 versus -6±109 steps per hour), but these differences were not statistically significant. Investigators concluded SE results in superior treadmill walking performance than ST, even for those with aortoiliac peripheral artery disease. The contrast between better walking performance for SE and better patient-reported quality of life for ST warrants further study.
Gardner et al (2011) reported on a prospective, randomized, controlled clinical trial compared changes in exercise performance and daily ambulatory activity in PAD patients with intermittent claudication after a home-based exercise program, a supervised exercise program, and usual-care control. Of the 119 patients randomized, 29 completed home-based exercise, 33 completed supervised exercise, and 30 completed usual-care control. Both exercise programs consisted of intermittent walking to nearly maximal claudication pain for 12 weeks. Patients wore a step activity monitor during each exercise session. Primary outcome measures included claudication onset time and peak walking time obtained from a treadmill exercise test; secondary outcome measures included daily ambulatory cadences measured during a 7-day monitoring period. Adherence to home-based and supervised exercise was similar and exceeded 80%. Both exercise programs increased claudication onset time and peak walking time, whereas only home-based exercise increased daily average cadence. No changes were seen in the control group. The changes in claudication onset time and peak walking time were similar between the 2 exercise groups, whereas the change in daily average cadence was greater with home-based exercise. Investigators concluded a home-based exercise program, quantified with a step activity monitor, has high adherence and is efficacious in improving claudication measures similar to a standard supervised exercise program. Furthermore, home-based exercise appears more efficacious in increasing daily ambulatory activity in the community setting than supervised exercise.

Imfeld et al (2006) provided first QoL data after PAD rehabilitation or a home-based PAD training in a non-randomized, open-label study. Three groups of out-patients were compared: group 1 (n = 18) PAD rehabilitation; group 2 (n = 17) PAD rehabilitation + clopidogrel 75 mg once daily; group 3 (n = 20) home-based training. The training period was 3 months, which was followed by a 3-month observation phase (without prescribed training). The institution-based rehabilitation program consisted of 3 training hours per week whereas patients training at home were instructed to walk for 1 hour per day on an outdoor track. QoL assessment was performed using MOS SF-36, PAVK-86 and PAD-WIQ questionnaires. At baseline background variables, demographics and claudication distances were comparable between groups. After three months of training the percentage changes for the initial and the absolute claudication distance (ICD, ACD) for groups 1, 2, and 3 amounted to 164%, 201%, 44% (ICD) and 83%, 131%, 5% (ACD), respectively. Statistically significant QoL improvements were recorded for physical functions, pain and disease related anxiety in all three study groups; statistically significant inter-group differences were not found. Investigators concluded in sharp contrast to the development of the claudication distances the improvement in QoL, found after 3 months of training, was comparable and not consistently different between the groups pilot study.

**Other Potential Indications**

Śmiałek et al (2013) reports that it has been demonstrated that patients with implantable cardioverter-defibrillator (ICD) are characterized by worse quality of life (QOL) and exercise capacity and are prone to depressive symptoms. Thus, comprehensive rehabilitation is indicated in ICD recipients. They sought to evaluate safety and benefits of comprehensive CR early after ICD implantation. The study group consisted of 45 patients (28 males, mean age 62.2 years) in whom a program of comprehensive cardiac rehabilitation was initiated at 6 weeks after ICD implantation. Rehabilitation consisted of two phases: 2-week inpatient Phase I and 12-week outpatient Phase II. Before and after the rehabilitation program, all patients were evaluated with transthoracic echocardiography, treadmill spiroergometric exercise test according to the modified Naughton protocol, a Polish version of the SF-36 questionnaire to assess QOL, and the Beck Depression Inventory (BDI) for
depressive symptoms. No deaths during the study and no complications or adverse events during rehabilitation or exercise testing were noted. Following comprehensive cardiac rehabilitation, we found an increase in left ventricular ejection fraction (30.09 ± 12.75 vs. 35.43 ± 13.4%; p = 0.002), peak oxygen uptake (VO\(_2\)) (21.3 ± 9.2 vs. 24.2 ± 10.3 mL/kg/min; p = 0.007) and duration of exercise (9.14 ± 3.7 vs. 9.53 ± 3.8 min; p < 0.05). An improvement was also noted in terms of depressive symptoms, as BDI score decreased (14.81 ± 9.27 vs. 12.83 ± 10.75; p = 0.020). QOL improved (p < 0.05), particularly the physical index (p = 0.02), as was the New York Heart Association class (p < 0.001). Improvement in peak VO\(_2\) was associated with better QOL (SF-total, r = -0.34; and physical index, r = -0.36). We also found a correlation between alleviation of depressive symptoms (BDI score) and improvement of QOL (SF-total, r = 0.52). Investigators concluded an improvement in left ventricular systolic function, exercise capacity and QOL and a reduction of depressive symptoms were observed in patients who took part in a program of early comprehensive cardiac rehabilitation after ICD implantation. No complications or side effects during rehabilitation sessions or exercise tests were observed in the study group.

Prior et al (2011) reported that comprehensive CR has not typically been used with cerebrovascular populations, despite important commonalities with heart patients. The authors tested feasibility and effectiveness of 6-month outpatient CCR for secondary prevention after transient ischemic attack or mild, nondisabling stroke. This article presents risk factors. A future article will discuss psychological outcomes. Consecutive consenting subjects having sustained a transient ischemic attack or mild, nondisabling stroke within the previous 12 months (mean, 11.5 weeks; event-to-CCR entry) with ≥1 vascular risk factor, were recruited from a stroke prevention clinic providing usual care. They measured 6-month CCR outcomes following a prospective cohort design. Of 110 subjects recruited from January 2005 to April 2006, 100 subjects (mean age, 64.9 years; 46 women) entered and 80 subjects completed CCR. We obtained favorable, significant intake-to-exit changes in: aerobic capacity (+31.4%; P<0.001), total cholesterol (-0.30 mmol/L; P=0.008), total cholesterol/high-density lipoprotein (-11.6%; P<0.001), triglycerides (-0.27 mmol/L; P=0.003), waist circumference (-2.44 cm; P<0.001), body mass index (-0.53 kg/m\(^2\); P=0.003), and body weight (-1.43 kg; P=0.001). Low-density lipoprotein (-0.24 mmol/L), high-density lipoprotein (+0.06 mmol/L), systolic (-3.21 mm Hg) and diastolic (-2.34 mm Hg) blood pressure changed favorably, but nonsignificantly. A significant shift toward nonsmoking occurred (P=0.008). Compared with intake, 11 more individuals (25.6% increase) finished CCR in the lowest-mortality risk category of the Duke Treadmill Score (P<0.001). Investigators concluded comprehensive CR is feasible and effective for secondary prevention after transient ischemic attack or mild, nondisabling stroke, offering a promising model for vascular protection across chronic disease entities. They noted a there has been no similar previous investigation, and are now conducting a randomized trial.

Clinical trials are underway to evaluate cardiac rehabilitation for various indications.
Outpatient Cardiac Rehabilitation Jan 17

Review History
April 2014 Medical Advisory Council, initial approval
Dec. 2014 Update – Added Ornish Cardiac Rehabilitation Program as investigational. Codes updated.
January 2017 Update – no changes

This policy is based on the following evidence-based guidelines:


References Update – December 2015

References Update – December 2014
5. Ornish D. Avoiding revascularization with lifestyle changes: The Multicenter Lifestyle Demonstration Project. Am J Cardiol 82. 72T-76T.1998; Abstract

References Initial


Important Notice

General Purpose.
Health Net's National Medical Policies (the "Policies") are developed to assist Health Net in administering plan benefits and determining whether a particular procedure, drug, service or supply is medically necessary. The Policies are based upon a review of the available clinical information including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the drug or device, evidence-based guidelines of governmental bodies, and evidence-based guidelines and positions of select national health professional organizations. Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member’s contract, including medical necessity requirements. Health Net may use the Policies to determine whether under the facts and circumstances of a particular case, the proposed procedure, drug, service or supply is medically necessary. The conclusion that a procedure, drug, service or supply is medically necessary does not constitute coverage. The member’s contract defines which procedure, drug, service or supply is covered, excluded, limited, or subject to dollar caps. The policy provides for clearly written, reasonable and current criteria that have been approved by Health Net's National Medical Advisory Council (MAC). The clinical criteria and medical policies provide guidelines for determining the medical necessity criteria for specific procedures, equipment, and services. In order to be eligible, all services must be medically necessary and otherwise defined in the member's benefits contract as described this "Important Notice" disclaimer. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to practice medicine.

Policy Effective Date and Defined Terms.
The date of posting is not the effective date of the Policy. The Policy is effective as of the date determined by Health Net. All policies are subject to applicable legal and regulatory mandates and requirements for prior notification. If there is a discrepancy between the policy effective date and legal mandates and regulatory requirements, the requirements of law and regulation shall govern. * In some states, prior notice or posting on the website is required before a policy is deemed effective. For information regarding the effective dates of Policies, contact your provider representative. The Policies do not include definitions. All terms are defined by Health Net. For information regarding the definitions of terms used in the Policies, contact your provider representative.

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Health Net reserves the right to amend the Policies without notice to providers or Members. In some states, prior notice or website posting is required before an amendment is deemed effective.

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The Policies do not constitute medical advice. Health Net does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Policy Limitation: Legal and Regulatory Mandates and Requirements
The determinations of coverage for a particular procedure, drug, service or supply is subject to applicable legal and regulatory mandates and requirements. If there is a discrepancy between the Policies and legal mandates and regulatory requirements, the requirements of law and regulation shall govern.

**Reconstructive Surgery**

CA Health and Safety Code 1367.63 requires health care service plans to cover reconstructive surgery. "Reconstructive surgery" means surgery performed to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease to do either of the following:

1. To improve function or
2. To create a normal appearance, to the extent possible.

Reconstructive surgery does not mean "cosmetic surgery," which is surgery performed to alter or reshape normal structures of the body in order to improve appearance.

Requests for reconstructive surgery may be denied, if the proposed procedure offers only a minimal improvement in the appearance of the enrollee, in accordance with the standard of care as practiced by physicians specializing in reconstructive surgery.

**Reconstructive Surgery after Mastectomy**

California Health and Safety Code 1367.6 requires treatment for breast cancer to cover prosthetic devices or reconstructive surgery to restore and achieve symmetry for the patient incident to a mastectomy. Coverage for prosthetic devices and reconstructive surgery shall be subject to the co-payment, or deductible and coinsurance conditions, that are applicable to the mastectomy and all other terms and conditions applicable to other benefits. "Mastectomy" means the removal of all or part of the breast for medically necessary reasons, as determined by a licensed physician and surgeon.

**Policy Limitations: Medicare and Medicaid**

Policies specifically developed to assist Health Net in administering Medicare or Medicaid plan benefits and determining coverage for a particular procedure, drug, service or supply for Medicare or Medicaid members shall not be construed to apply to any other Health Net plans and members. The Policies shall not be interpreted to limit the benefits afforded Medicare and Medicaid members by law and regulation.